K002037

Section 11: Premarket Notification 510(k) Summary

1. *Submitter's Name / Contact Person*

Carolyn Anderson
Regulatory Specialist
Lifecore Biomedical, Inc.
Ph: 952-368-6324

Date Submission Prepared: June 30, 2000

2. *General Information*

Trade Name	Restore® RBM Self-Tapping Regular Diameter Dental Implant
Common / Usual Name	Dental Implant
Classification Name	Endosseous Implant (21CFR 872.3640)
Identification of Equivalent Devices	▪ Brånemark System® Implants, indicated for Immediate Loading, manufactured by Nobel Biocare (K992930) ▪ ITI One-Part Dental Implant System manufactured by Institut Straumann (K984104)

3. *Device Description*

The Restore® Resorbable Blast Media (RBM) Self-Tapping Regular Diameter Dental Implants are screw type root-form implants manufactured from commercially pure titanium. The Restore RBM Implants are available in diameters of 3.75mm to 4.0mm and in lengths ranging from 8mm to 15mm.

4. *Intended Use*

Restore RBM Self-Tapping Implants are intended for use in the completely edentulous or partially edentulous patient maxilla or mandible, for use as support for prosthetic restoration. The restoration can be fixed detachable, cemented, overdenture or freestanding restoration that is implant or soft tissue supported. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

If a single stage surgical procedure is used, implants may be loaded immediately following insertion, provided at least four implants are placed, and are splinted together. These implants must be placed in the anterior mandible where good initial stability of the implants can most often be obtained.

5. Technological Characteristic Comparisons

Feature	Subject Device	Predicate Devices	
	Restore RBM Self-Tapping Implants	ITI One-Part Dental Implant	Brånemark System® Implants
510(k) Number:	NA	K984104	K992937
Intended Use:	Functionally, the same as the predicates: The Lifecore Biomedical Dental Implant products listed above are intended for use in the completely edentulous or partially edentulous patient, maxilla or mandible for use as support for prosthetic restoration	Intended to be placed in the maxillary and/or mandibular arches to support prosthetic restorations in edentulous or partially edentulous patients.	Intended to be placed in the upper or lower jaw to support prosthetic devices such as artificial teeth, and to restore patient's chewing function.
Indications For Use:	Immediate Load: "Lifecore Biomedical Dental Implant Systems are intended for use in the completely edentulous or partially edentulous patient, maxilla or mandible for use as support for prosthetic restoration. The restoration can be fixed detachable, cemented, overdenture or freestanding restoration that is implant or soft tissue supported. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. If a single stage surgical procedure is used, implants may be loaded immediately following insertion, provided at least four implants are placed, and are splinted together These implants must be placed in the anterior mandible where good initial stability of the implants can most often be obtained.	Immediate Load: "ITI One Part octa implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. ITI one-part octa implants are for use in edentulous jaws in conjunction with bar-borne superstructure on 4 implants. If ITI one-part implants are splinted with a bar, they can be loaded immediately. ITI one-part implants can also be used for indications requiring endosseous implants for functional rehabilitation in regions where an ITI two-part and an Octa abutment would normally be used."	Immediate Load: "Selected Branemark System implant products are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. If a single stage surgical procedure is used, these implants may be loaded immediately following insertion – provided – at least four implants are placed, and are splinted with a bar. These implants must be placed predominately in the anterior mandible (between the mental foramina) where good initial stability of the implants, with or without bi-cortical anchorage can most often be obtained."

Feature	Subject Device	Predicate Devices	
	Restore RBM Self-Tapping Implants	ITI One-Part Dental Implant	Brånemark System® Implants
510(k) Number:	NA	K984104	K992937
Material:	CP Titanium	CP Titanium	CP Titanium
Design	Threaded root-form implant	Threaded, transmucosal root-form implant	Threaded root-form implant
Surface treatment	RBM	Roughened surface, method unknown	Uncoated
Implant Body Diameter (mm)	3.75, 4.0	4.1, 4.8	3.75, 4.0
Lengths	8 to 15mm	8mm to 14mm	10 to 21mm
Sterilization	Gamma	Unknown	Dry heat or steam

6. Nonclinical Tests

No modifications were made to the device, materials, or to the manufacturing, packaging or sterilization procedures. Therefore, additional nonclinical testing was not required.

7. Conclusion (statement of equivalence)

The data submitted in this 510(k) is in support of substantial equivalency of the Restore® Resorbable Blast Media (RBM) Self-Tapping Regular Diameter Dental Implant to the following commercially marketed devices:

- ITI One-Part Dental Implant System (K984104)
- Brånemark System® Implants (K992937)

These current products as defined by their product literature, demonstrate the basis for the substantial equivalency relative to indications, materials, design, and surface characteristics. The intended use of these devices is functionally the same as the Lifecore Biomedical Dental Implants. The comparative analysis demonstrates the substantial equivalence of the Restore® Resorbable Blast Media (RBM) Self-Tapping Regular Diameter Dental Implants to the predicate devices that are in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2001

Ms. Carolyn Anderson
Regulatory Specialist
Lifecore Biomedical, Incorporated
3515 Lyman Boulaverd
Chaska, Minnesota 55318

Re: K002037
Trade/Device Name: Restore® Regular Diameter RBM Dental Implant System
Regulation Number:
Regulatory Class: III
Product Code: DZE
Dated: February 14, 2001
Received: February 15, 2001

Dear Ms. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment D: Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002037

Device Name:
Restore® Regular Diameter RBM Dental Implant System:

Indications for Use:

Restore® Regular Diameter RBM Dental Implant System is intended for use in the completely edentulous or partially edentulous patient, maxilla or mandible for use as support for prosthetic restoration. The restoration can be fixed detachable, cemented, overdenture or freestanding restoration that is implant or soft tissue supported. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

If a single stage surgical procedure is used, implants may be loaded immediately following insertion, provided at least four implants are placed, and are splinted together. These implants must be placed in the anterior mandible where good initial stability of the implants can most often be obtained

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002037